EXHIBIT 56

Chapter 10
OTHER PROCEDURES

This chapter includes the following sections:

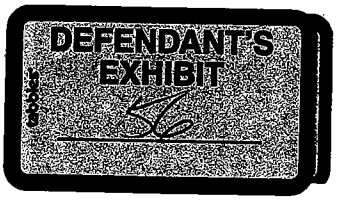
10-1 COMMUNICATIONS – DISTRICT AND CENTER RESPONSIBILITIES

10-1-1 Regulatory Actions that Require Center Concurrence

When a decision is made by the District that initiation of a regulatory action is appropriate, the District should notify the appropriate Center compliance unit regarding its intent to submit a recommendation. District Compliance staff should also remember to enter the "In Review" profile status as "pending" on the Maintain Profiles screen in the Field Accomplishment and Compliance Tracking System (FACTS) for each profile class covered when the recommendation is a result of a Current Good Manufacturing Practice (CGMP) or Quality System (QS) inspection of a domestic drug, biologics, or medical device facility. Compliance staff should also notate the Remarks field to explain the action being recommended. When the action recommendation is forwarded to a Center for review, the Remarks field should be updated to reflect that and include the date forwarded. With regard to foreign inspections, Center Compliance staff are responsible for the review and evaluation, and should enter the In Review "pending" status and notate the corresponding Remarks field as appropriate. (See "Firm Profile Updates in FACTS" in Chapter 4 for more information.)

The Center will notify the District as soon as a case (compliance) officer has been assigned. This early communication will create opportunities to discuss the case, including the overall strategy, as well as the history, violations, rationale, charging scheme, regulatory and policy considerations, local knowledge, and national/program issues.

If, after its initial review of a District's recommendation, the Center compliance unit is inclined not to concur with the District's recommendation, the Center will promptly notify and provide the District with an oral explanation for its preliminary decision not to concur with the



recommendation. If the District does not agree with the basis for the potential disapproval, it should provide the Center with additional justification for proceeding with the recommended action within three business days. The additional justification should be limited to information currently available to the District, not a commitment to gather additional information to support the recommendation. The Center will consider this additional justification before making a final disposition on the District's recommendation, apprise the District of its decision, and prepare the final memo. The Center's final disposition on the recommendation (approved or disapproved) will normally not be delayed if it is determined that an inspection will be necessary to collect additional supporting evidence. The involved compliance officer and the DCB should participate in discussions with the Center that occur during the process described in this paragraph. If the official action proposed was not the subject of a formal recommendation from the District (e.g. BIMO, foreign inspection), the same communication principles should apply between involved Center and District staff.

10-1-2 Regulatory Actions prepared by a Center for District Issuance and/or Follow-up

When a decision is made by a Center that District issuance, involvement and/or follow-up is an appropriate course of action, the Center should notify the appropriate District compliance unit(s) regarding its intent to prepare a regulatory action, and provide the District(s) with an opportunity to collaborate on the compliance strategy and the substance of the action.

10-1-3 Debarment - Notification Responsibilities of FDA Employees

1. ***Background***

   a. Purpose and Authority for Debarment - Debarment is a remedial measure taken under section 306 of the Act to prohibit a person (e.g., an individual, corporation, partnership, or association) from participating in FDA-regulated activities, as described below:

      i. A person other than an individual may be prohibited from submitting, or assisting in the submission of, any abbreviated drug application. Sections 306(a)(1) and 306(b)(1)(A).

      ii. An individual may be prohibited from providing services in any capacity to the sponsor of an approved or pending drug product application. Sections 306(a)(2) and 306(b)(1)(B).

      iii. A person may be prohibited from importing an article of food, or offering an article of food for import, into the United States. Section 306(b)(1)(C).

      iv. A person may be prohibited from being accredited to inspect eligible device manufacturers and from carrying out activities under agreements with foreign countries to facilitate commerce in devices. Section 306(m)(1).

      Debarment may be based on a criminal conviction or on conduct, as identified in section 306 of the Act. See "Persons Subject to Debarment" below.

   b. "Drug Product" - For purposes of section 306, the term "drug product" means a drug

subject to regulation under section 505 (new drugs), section 512 (new animal drugs), or section 802 (exports of certain unapproved products) of the Act, or under section 351 (regulation of biological products) of the Public Health Service Act. Section 201(dd).

c. Other Possible Actions - Civil Penalties

Under section 307(a)(6) of the Act, any person with an approved or pending drug product application who knowingly engages the services of a debarred person is liable for civil penalties.

Under 307(a)(7), debarred individuals are subject to civil penalties for providing services to a person with an approved or pending drug product application.

2. ***Notification Responsibilities***

a. Authority - Staff Manual Guide (SMG) "7712 - Debarment Proceedings" provides general procedures for FDA staff to follow for debarment actions and defines the responsibilities of FDA employees. ORA's Office of Enforcement (OE) has responsibility for initiating and pursuing debarment actions. All FDA employees have a responsibility to notify OE of any persons that may be subject to debarment and to forward relevant materials to OE within specified timeframes, as detailed below.

b. Required Notification - In accordance with SMG 7712, all FDA employees have the following responsibilities:

i. Ensuring that ORA's Office of Enforcement (OE) is notified when the employee has notice (from an oral or written communication) that a person may be subject to debarment.

ii. Ensuring that OE is provided with copies of all relevant materials (e.g., any written notice or petition for debarment and information supporting debarment) in the employee's possession.

Send the notification and materials to the attention of the Debarment Specialist, Division of Compliance Policy/OE via electronic transmission, interoffice or regular mail, or FAX. Include your name, office, and phone number. The Division of Compliance Policy (DCP) is located at 15800 Crabbs Branch Way, Suite 130, Rockville, Maryland 20855. Mail code HFC-230. Telephone 240-632-6860; FAX 240-632-6861. Contact the Debarment Specialist or DCP if you have any questions about notification or debarment, or if you need further information.

c. Timeframes for Notification - If the person who may be subject to debarment:

i. has an approved or pending drug application;

ii. is an employee of such a person;

iii. is a clinical investigator;

iv. is currently engaged in importing food or offering it for import; or

v. has been convicted of a felony under section 301(gg) of the Act, FDA employees will notify OE as soon as is practicable.

Otherwise, employees will notify OE within ninety (90) days of receiving the oral or written notice.

d. Requirements Applicable to OCI - The Office of Criminal Investigations (OCI) is responsible for providing quarterly reports to the Director, Division of Compliance Policy (OE) that set forth all convictions that have occurred within the preceding three (3) months that may trigger debarment.

3. ***Persons Subject to Debarment***

The triggering event for debarment is ordinarily a felony or misdemeanor conviction under Federal law or a felony conviction under State law. However, certain conduct may subject a food importer, and, for drugs and biologics, a high managerial agent (and other individuals) to debarment. The types of convictions and conduct that may subject persons to debarment are detailed in section 306 of the Act and summarized below, by product type.

a. Foods: A person (an individual, corporation, partnership, or association) is subject to debarment if the person has been convicted of a felony for conduct relating to the importation into the U.S. of any food, or has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals. Section 306(b)(3).

b. Drugs – Corporations, Partnerships, and Associations: A person other than an individual is subject to debarment if that person has been:

i. Convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any abbreviated drug application. Section 306(a)(1).

ii. Convicted for conduct that relates to the development or approval, including the process for development or approval, of any abbreviated drug application, and is a misdemeanor under Federal law or a felony under State law. Section 306(b)(2)(A)(i).

iii. Convicted of a conspiracy to commit, or aiding or abetting, a criminal offense described in i. or ii. above. Section 306(b)(2)(A)(ii).

c. Drugs/Biologics – Individuals: An individual is subject to debarment if s/he has been:

i. Convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product, or otherwise relating to the regulation of any drug product under the Act. Section 306(a)(2).

ii. Convicted of a misdemeanor under Federal law or a felony under State law for conduct relating to the development or approval, including the process for development or approval, of any drug product, or otherwise relating to the regulation of drug products under the Act, or has been convicted of a conspiracy to commit, or aiding or abetting, a criminal offense described in this paragraph or the preceding paragraph. Section 306(b)(2)(B)(i).

iii. Convicted of a felony under Federal law or a felony under State law which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense, or a conspiracy to commit, or aiding or abetting, such felony. Section 306(b)(2)(B)(ii).

d. Drugs/Biologics – Debarment based on Conduct: An individual is also subject to debarment:

i. If s/he materially participated in acts that were the basis for a conviction for an offense subject to debarment. Section 306(b)(2)(B)(iii).

ii. If s/he is a high managerial agent who:

- worked for, or worked as a consultant for, the same person as another individual during the period in which such other individual took actions for which a felony conviction was obtained and which resulted in the debarment of such individual;
- had actual knowledge of the actions described above of such other individual, or took action to avoid such actual knowledge, or failed to take action for the purpose of avoiding such actual knowledge;
- knew that the actions were violative of law; and
- did not report such actions, or did not cause such actions to be reported, to an officer, employee, or agent of the Department or to an appropriate law enforcement officer, or failed to take other appropriate action that would have ensured that the process for the regulation of drugs was not undermined, within a reasonable time after such agent first knew of such actions. Sections 201(bb) and (cc), and 306(b)(2)(B)(iv).

e. Devices: A person (an individual, corporation, partnership, or association) accredited to inspect eligible device manufacturers is subject to debarment if the person has been convicted of a felony for one or more prohibited acts under section 301(gg) of the Act. Section 306(m).

Section 301(gg) prohibits the knowing failure to notify the Secretary of a condition the accredited person discovered during an inspection that could cause or contribute to an unreasonable risk to the public health as required by section 704(g)(7)(E), or an accredited person's knowing inclusion of false information in an inspection report prepared under section 704(g)(7)(A), or the knowing failure to include material facts in such a report.

10-2 PRIOR NOTICE

10-2-1 Purpose

This section defines "prior notice" and establishes uniform criteria to determine if adequate prior notice has been provided.

10-2-2 Background

Except in a few specifically defined areas, the Food and Drug Administration (FDA) has no legal obligation to warn firms or individuals that they, their practices, or their products are in violation of the law prior to taking formal enforcement action. However, a basic principle of FDA's enforcement policy is the belief that the majority of persons will voluntarily comply with the law when given information as to what is required, what violations appear to exist, and, in the case of violations of regulatory significance, that failure to comply may result in the initiation of enforcement action.

10-2-3 Policy

When it is consistent with the public protection responsibilities of the agency and if a violative situation does not present a danger to health or does not constitute intentional, gross or flagrant violations, it is FDA's policy to afford individuals and firms an opportunity to voluntarily take appropriate and prompt corrective action prior to the initiation of enforcement action. If voluntary correction is not achieved, documentation that adequate prior notice was provided strengthens the agency's position in enforcement actions by establishing that responsible individuals continued violating the law despite having been warned by the agency.

The following factors should be considered in evaluating the adequacy of prior notice (prior warning):

1. The conduct, condition, practice, or product violates the laws enforced by FDA.
2. The notice (warning) adequately identified the violative conduct, condition, practice or product. (Note: Similar violations do not need separate prior notices, for example, separate prior notices are not necessary for each unapproved new drug shipped.)
3. Notice (warning) was provided to the firm and the most responsible individuals.
4. The firm was afforded a reasonable amount of time to implement corrections. Corrections may include halting shipments, recalling product in violation, or changing procedures and controls.
5. Consider if situations have occurred that may affect the adequacy of prior notice, such as a change in ownership or responsible management. For example, consider what is known by the new management, and if the "firm" received notice.

Note: Prior Notice may be provided orally or in writing. Where there is no dispute as to what is required to comply with the law, adequate notice may well be the Investigator's discussion of objectionable conditions with responsible management at the conclusion of the inspection. If, however, the violative conduct involves a controversial area, an area in which policy is still emerging, or one that has not been pervasively regulated in the past, written notice (usually in the form of a Warning Letter) may be required prior to the initiation of further enforcement action.

Consideration of these factors will facilitate meeting the prior notice requirements for civil and certain criminal actions.

10-2-4 Procedures

Warning Letters are the principal means by which the agency provides prior notice of violations and of achieving voluntary compliance. See RPM Chapter 4, Advisory Actions. However, Prior Notice may be provided by means of a civil suit, administrative action, or other less formal ways, including the following:

1. Enforcement action or notification by State, municipal or other Federal agencies involving the same or similar violations.
2. Issuance of the FDA-483, List of Observations, at the conclusion of an inspection. Issuance of a copy of the FDA-483 to a firm's most responsible person(s) must follow guidance in Field Management Directive 120.
3. Discussion with management by an FDA investigator, documented in the EIR.
4. Recall Classification Notification Letters.
5. Properly documented meetings or telephone conversations between agency officials and a firm's top management (see section on Regulatory Meetings in this chapter).
6. Properly documented advisory communications by FDA Center personnel concerning critical scientific issues.

Note: For further information related to "properly documented" telephone conversations and meetings, see Staff Manual Guide, External Relations, Guide 2126.2, Memoranda of Telephone Conversations and Meetings with Non-FDA Persons, on the OIRM Intranet site.

10-3 REGULATORY MEETINGS

A Regulatory Meeting is a meeting requested by FDA management at its discretion, to inform responsible individuals or firms about how one or more products, practices, processes, or other activities are considered to be in violation of the law. FDA is not required to hold a Regulatory Meeting and, except for a few specifically defined areas (see RPM Chapter 4 – Warning Letter Procedures), is not required to provide any other form of prior notice prior to taking an enforcement action (see RPM Chapter 10).

Regulatory Meetings can be an effective enforcement tool to obtain prompt voluntary compliance, and have been used successfully in a variety of different situations, including:

1. As a follow-up to a Warning Letter when firms have corrected the majority of violative conditions noted in the Warning Letter, to provide additional encouragement, direction, and assistance in achieving compliance. As a follow-up to a Warning Letter, FDA officials may remind a firm or individual in a Regulatory Meeting that failure to make appropriate corrections in a timely manner may result in enforcement action.
2. To communicate documented violations that do not warrant the issuance of a Warning Letter. Under these circumstances, a Regulatory Meeting provides the added benefit of real time, two-way discussion of the violations and the appropriate corrective actions.

A Regulatory Meeting should not be used as a substitute for an Untitled Letter when a particular compliance program calls for the issuance of an Untitled Letter. Also, in most cases, a Regulatory Meeting should not be used to initially communicate violations of regulatory significance. Such violations are generally best communicated in the form of a Warning Letter. However, there are some situations when a regulatory meeting may be used to initially communicate violations of regulatory significance. Examples include:

1. When a Regulatory Meeting is held to communicate a health hazard and the necessity for immediate corrective action to address violative product that is on the market.

2. When a Regulatory Meeting is held in conjunction with the issuance of a Warning Letter to emphasize the significance of the violations.

A successful outcome of a Regulatory Meeting would include a commitment by the responsible individuals to correct the conditions or practices at their facility that are in violation of the law. The districts, at their discretion, would typically verify these commitments through evaluation of subsequent communication and documentation and/or a follow-up inspection. The inspection classification should reflect the significance of the violations and can be appropriately modified based on the adequacy of the corrective action. In those instances where the corrective actions are not satisfactorily carried out, definitive plans should be made for follow up action by the District. Consult with the involved Center and OE is advisable.

Any FDA organization with regulatory oversight of a firm or individual has the discretion to decide whether or not to hold a Regulatory Meeting. If a Center decides to hold a Regulatory Meeting concerning observations made by one or more Districts, the Center should invite any districts involved and consider any objections that such district(s) may have to such meeting. Centers are also encouraged to invite district participation in Regulatory Meetings concerning observations or matters originating in the Center (e.g., unapproved new drug or device issues). Any disagreement between a Center and a District about whether to conduct a Regulatory Meeting should be resolved by collaborative discussion with the Center, District, and OE.

For situations that involve corporate-wide violations or multiple districts, the meeting should include the affected Centers, OE, and the involved Districts. The location of the meeting should be negotiated by the involved parties.

Summary minutes must be prepared for all regulatory meetings.

10-4 INSPECTION OF FOOD RECORDS – SECTIONS 414(a) and 704(a)

10-4-1 Purpose

This section describes the authority, criteria, and procedure for inspecting records under sections 414(a) and 704(a) of the Federal Food, Drug, and Cosmetic Act.

10-4-2 Authority

1. ***The Federal Food, Drug, and Cosmetic Act (the Act):***

   a. Section 414(a) "Records Inspection" – If the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, FDA can access and copy all records relating to the manufacture, processing, packing, distribution, receipt, holding, or

importation of the food that are needed to assist the Secretary in making such a determination – with the following exclusions and conditions:

i. Applies to any person - *excluding farms and restaurants* - who manufactures, processes, packs, distributes, receives, holds, or imports an article meeting the above criteria.

ii. Applies to all records maintained by or on behalf on such person in any format and at any location - *excluding recipes, financial data, pricing data, personnel data, research data, and sales data* (other than shipment data regarding sales). Section 414(d)(4).

iii. Appropriate credentials and a written notice must be presented and the inspection must be conducted at reasonable times, within reasonable limits, and in a reasonable manner. See "Issuing the FDA 482c" below.

b. Section 414(b) provides authority for the Secretary to promulgate regulations to establish requirements for the establishment and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food. These regulations are found in 21 CFR Part 1, Subpart J, §§ 1.326 through 1.368.

c. Section 704(a) requires any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods to provide access to all records and other information described in section 414 when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

d. Section 301(e) makes it a prohibited act to refuse to permit access to or copying of any record required by section 414; or to fail to establish or maintain any record required by section 414(b).

2. ***21 CFR §§ 1.326 through 1.368***. These regulations require the establishment and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food; and require records to be made available, as follows:

a. 21 CFR 1.361 - When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the act must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the request.

10-4-3 Criteria for Invoking Records Inspection Authority

The authority to access and copy records can be invoked whenever the statutory criteria are satisfied, whether or not intentional adulteration is known or suspected. That is, FDA can access and copy records if: (1) the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, and (2) the records are necessary to assist the Secretary in making such a

determination.

The authority to access and copy records can not to be invoked unless the statutory criteria above are satisfied.

10-4-4 Records that may be accessed and copied under this authority

Records associated with an article(s) of food that meet the statutory criteria may be requested. These records may be related to the manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of such food that are maintained by or on behalf of an entity subject to the recordkeeping regulation. The records may be in any format (including paper and electronic formats) and at any location. Because the circumstances of a particular event are case specific, the scope of a record request will vary on a case-by-case basis. Depending upon the circumstances, the authority under sections 414(a) and 704(a) of the Act may apply to some or all records that are required to be kept by regulation under section 414(b) to determine the immediate previous sources and the immediate subsequent recipients of food.

10-4-5 Records that may *not* be accessed and copied under this authority

FDA's authority under sections 414 and 704(a) of the Act does not apply to records excluded under section 414(d) (e.g., recipes for food, financial data, pricing data, personnel data, research data, or sales data other than shipment data regarding sales) and records from farms and restaurants. 21 CFR 1.328 defines a "recipe" as "the formula, including ingredients, quantities, and instructions necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe." Accordingly, FDA has authority to access such a list of ingredients in a records request.

10-4-6 Procedure for Invoking Records Inspection Authority

Concurrence must be obtained in accordance with the procedures below before making a request to any party for access to records under sections 414(a) and 704(a).

1. District (or other FDA) personnel notify FDA's Emergency Operations Center (EOC at 301-443-1240 - 24 hours/day), which coordinates the emergency response activities associated with a food article that may present a threat of serious adverse health consequences or death to humans or animals.

   (**Note**: Steps 2-6 may occur concurrently or sequentially)

2. EOC notifies the appropriate Center (CFSAN and/or CVM) and the Office of Enforcement (OE) in the Office of Regulatory Affairs (either verbally or in writing).

3. The appropriate Center, with the concurrence of OE, determines that there is a reasonable belief that an article of food is adulterated and that the food presents a threat of serious adverse health consequences or death to humans or animals.

4. OE concurs with any requests for access to records, and works with the appropriate Center to determine the scope of the request and ensure the requested records are necessary to assess whether a food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

5. The appropriate Center consults with the Office of Chief Counsel (OCC) on the determination of whether there is a reasonable belief an article of food is adulterated. OE will consult with OCC on the scope of the records request.

6. Once all the necessary determinations are made, OE conveys the information to the Director of the district in which the facility being inspected is located.

10-4-7 Issuing the FDA 482c

After the necessary determination has been made in accordance with the procedures above, an investigator or other FDA personnel upon presentation of credentials will submit a written notice, Form FDA 482c, to the owner, operator, or agent in charge, and inform that person of the records requested and FDA's legal authority to obtain these records. FDA may request additional records related to the implicated food article at a later time under the same authority.

10-4-8 Timeframes for compliance

Records and other information requested under this authority must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the request. 21 CFR 1.361.

10-4-9 Failure to provide records

The refusal to permit access to or copying of any record required by section 414, or the failure to establish or maintain any record required by section 414(b) is prohibited under Section 301(e) of the Act.

10-5 ESTABLISHMENT INSPECTION REPORT (EIR) CONCLUSIONS AND DECISIONS

For further information related to "EIR Conclusions and Decisions," see Field Management Directive No. 86, or refer to the web site at http://www.fda.gov/ora/inspect_ref/fmd/fmd86.htm.

Please remember to update the firm's FACTS profile information at each stage in the review process to its conclusion, as appropriate, for any Current Good Manufacturing Practice (CGMP) or Quality System (QS) inspection of a domestic or foreign drug, biologics, or medical device facility that involves compliance activity or status. See "Firm Profile Updates in FACTS" in Chapter 4 for further information.

10-6 INTERSTATE TRAVEL PROGRAM (ITP) CLASSIFICATIONS AND ADMINISTRATIVE ACTIONS

For further information related to ITP see Compliance Program 7318.029, "Interstate Travel Program-- Conveyances and Support Facilities" or visit the web site at http://www.cfsan.fda.gov/~comm/cp18029.html. In addition, see Field Management Directive No. 122, "Interstate Travel Sanitation: Potable Water on Interstate Carrier Conveyances and at Watering Points" or visit the web site at http://www.fda.gov/ora/inspect_ref/fmd/fmd122.htm.

10-7 REPORTING AND MONITORING

The Field Accomplishments and Compliance Tracking System (FACTS) replaces this section. Please see your FACTS Lead User for further guidance.

10-8 *AD HOC* COMMITTEE

10-8-1 Purpose

This section outlines the function, composition, and activities of agency ***ad hoc*** committees that are convened for enforcement purposes, and lists the responsibilities of the field and headquarters units in recommending and carrying out the goals of the ***ad hoc*** committee.

10-8-2 Background

In 1984, an Office of Planning and Evaluation (OPE) study of the routine and non-routine case procedure disclosed considerable support for the ***ad hoc*** committee system from agency managers and case reviewers. An updated 1986 OPE study demonstrated that the use of ***ad hoc*** committees expedited the processing of injunctions by resolving issues, planning regulatory procedures, and committing responsible units to an action plan.

10-8-3 Function

There are three principle types of ***ad hoc*** committees, "strategy," "referral," and "appeal."

1. Strategy ***ad hoc*** committees are formed to resolve issues for which agency precedent is lacking on matters that involve complex and difficult enforcement issues, or where there is a dispute between two or more offices over strategy.

2. Referral ***ad hoc*** committees are formed to consider the referral of a matter to the Department of Justice for further criminal investigations or proceedings. See Chapter 6, "Judicial Actions."

   Note: The Office of Criminal Investigations (OCI) is responsible for reviewing all matters within the scope of FDA for which a criminal investigation may be recommended. If the district or center office believes that there is a need for a criminal investigation, they must contact OCI immediately. If OCI concludes that they will not be participating in the matter at the time, the district office or center may then proceed as outlined below under "Procedures."

   Either type of ***ad hoc*** committee may be formed at any point in the case development or review process. However, early identification of the need for an ***ad hoc*** committee expedites subsequent decision-making and enables a more prompt review of legal actions. Every effort should be made to use this procedure in the early stages of a complex or difficult investigation, before enforcement action is recommended or fully developed.

3. An appeal ***ad hoc*** committee may also be convened when an agency component appeals an adverse decision (See APPEAL PROCESS) or disputes a regulatory course of action, because enforcement policy is inconsistent, unclear or non-existent. Before such an ***ad hoc*** is requested, the parties in disagreement should first attempt to resolve the disputed issues between themselves.

10-8-4 Composition

The ***ad hoc*** committee will be chaired by the Director, Office of Enforcement (OE), and will consist of the Regional Food and Drug Director (RFDD), the appropriate Center Director of Compliance, the Deputy Chief Counsel for Litigation and, if appropriate, the Director, OCI. These individuals are the "principals." When the principals are unable to participate in a scheduled ***ad hoc*** meeting, they must designate a senior compliance official (or attorney for the Office of Chief Counsel (OCC)) to serve in their absence.

The principals or their designated representatives should be prepared to make agency decisions on the issues based upon the evidence presented prior to and during the ***ad hoc*** meeting. The principals are also responsible for identifying and arranging for the participation of any appropriate resource persons they feel are necessary. Resource persons should be limited to those individuals who have knowledge of the events at issue or who can significantly help in the decision making process.

10-8-5 Procedures

Requests for forming an ***ad hoc*** committee may originate from an RFDD, a District Director (with RFDD concurrence), a Center Director of Compliance or its equivalent, the Director, Office of Regional Operations (ORO), the Director, OE, or the Deputy Chief Counsel for Litigation.

The requesting office must submit an **original and three copies** of the ***ad hoc*** request and supporting material to OE, Division of Compliance Management and Operations (DCMO), HFC-210. Except in case of an immediate emergency, the committee must be given at least ten working days to review the ***ad hoc*** request and the accompanying material.

The ***ad hoc*** request (consisting of an executive summary no greater than five pages in length) must provide the following information:

1. A brief factual background of the case or enforcement matter.
2. A description of the evidence that FDA has in hand, including pertinent exhibits (exhibits should be limited to the matter at issue).
3. For a strategy ***ad hoc***, the requesting office's recommended outcome of the ***ad hoc*** meeting.
4. For a referral ***ad hoc***, a description of the evidence expected to be gained through the grand jury and the reasons it is necessary to refer the matter to the grand jury instead of continuing with an FDA investigation.
5. For an appeal ***ad hoc,*** the appeal memorandum (RPM section 10-9-5) and a summary of DCMO attempts to gain resolution of the disagreement by the parties to the appeal.
6. A description of options previously considered, and the reasons those options were rejected.
7. Any other reasons for submitting the ***ad hoc*** request.

The meeting will be chaired by the Director, Office of Enforcement. The principal committee member requesting the ***ad hoc*** meeting will briefly summarize the reason for the request, the recommended outcome of the meeting, describe any foreseeable problems, and provide whatever additional information that may be useful in reaching a decision.

All decisions made by the ***ad hoc*** committee, including necessary follow-up and strategy, will be recorded and disseminated by the DCMO Compliance Officer assigned to the matter. The ***ad hoc*** committee may reconvene in cases of significant changes/revisions to the original ***ad hoc*** supporting material, the discovery of new information or evidence, or when other issues arise that could impact the original decision of the committee. If it is necessary to reconvene the ***ad hoc*** committee, the ***ad hoc*** principals attending the original meeting should make every effort to attend any follow-up ***ad hoc*** meeting.

In most instances, the committee will reach a decision through consensus of the members. When consensus is not possible, the Director, OE, will refer the matter to the Associate Commissioner for Regulatory Affairs (ACRA) with a recommendation for making a final decision. All committee decisions are subject to review by the ACRA and OCC, and the final decision will not be subject to appeal.

10-8-6 Responsibilities

OE/DCMO receives the request for convening an ***ad hoc*** committee, reviews and assesses the submission to determine if there is a clear indication of a dispute or other issue in need of resolution, determines that the supporting information is complete, establishes the time and place for the meeting, and disseminates supporting material to the principal members of the ***ad hoc*** committee.

The Director, OE, chairs the ***ad hoc*** committee and issues the final decision based upon the ***ad hoc*** committee's discussion. If the ***ad hoc*** committee cannot reach a decision, the Director, OE, refers the matter to the ACRA for a final decision.

The Director, ORO, may recommend convening an ***ad hoc*** committee based on issues that rise from ORO headquarters based program activities.

The RFDDs make a final decision on all recommendations for an ***ad hoc*** committee from the field. The Regional Director serves as a principal on the ***ad hoc*** committee.

The District Director may recommend the convening of an ***ad hoc*** committee and forward the recommendation with appropriate background information to OE through the RFDD.

The Center Director of Compliance or equivalent approves or disapproves all recommendations for an ***ad hoc*** committee from the center and will serve as a principal on the ***ad hoc*** committee.

The Deputy Chief Counsel for Litigation, OCC, will serve as a principal on the ***ad hoc*** committee to provide legal counsel.

Principals who are unable to participate in a scheduled ***ad hoc*** meeting are responsible for designating a senior compliance official to serve in their absence. The principals are also responsible for identifying and arranging for the participation of any appropriate resource persons they feel are necessary, and for providing necessary background information to those persons.

10-9 APPEAL PROCESS

10-9-1 Purpose

This section sets forth a procedure for the appeal of decisions regarding recommendations for

legal or administrative actions.

10-9-2 Who May Appeal

Appeals may be originated by the RFDDs or the Center Directors for Compliance (or equivalent).

10-9-3 What May Be Appealed

Appropriate officials may appeal any decision disapproving a proposed action, administrative or legal, which is allegedly inconsistent, or where there is nonexistent enforcement policy. The directors of the involved offices must have attempted to resolve the disagreement prior to submitting an appeal.

10-9-4 When An Appeal Is Not Appropriate

An appeal is not appropriate when additional information that overcomes the basis for the original denial becomes available. In such cases, the recommendation should be updated to include the new or additional information and resubmitted to the reviewing office with an explanation for the resubmission and a request for reconsideration.

10-9-5 Requests For Appeal

District offices should submit appeals over the signature of the RFDD. Centers should submit appeals over the signature of the Center Director for Compliance. The appeal memorandum and two copies of relevant supporting material must be identified, indexed, and submitted to the Director, OE (HFC-200).

The appeal memorandum must identify the issues on which the appeal is based, and the reasons for disagreeing with the decision of the declining unit. Recommendations must include a summary of communications regarding attempts to resolve differences of opinion.

10-9-6 Review Of Appeals

OE/DCMO will review the appeal package to assure that it is complete, determine that an appeal is appropriate, and will determine whether the appeal deals with policy, regulations, or a statute. DCMO will initially attempt to gain a resolution of the disagreement by the parties to the appeal.

10-9-7 Decision On Appeals

If DCMO cannot get the parties to agree, an ***ad hoc*** committee meeting to be chaired by the Director, OE, will be scheduled, following the procedures outlined in section 10-6, ***ad hoc*** Committee.

The meeting will include the RFDD, the Center Director for Compliance, and the Deputy Chief Counsel for Litigation, if appropriate. If the principals are unable to attend, they will designate a senior compliance official to serve in their absence. Usually only one resource person must accompany the senior compliance official.

Resolution of appeals is by consensus of the ***ad hoc*** committee members. If the ***ad hoc*** committee can not reach a consensus, the matter will be forwarded to the ACRA for a final decision.

Decisions made by the ***ad hoc*** committee will be recorded and distributed to meeting participants. The decision may be limited to a decision on the merits of the case or it may include instructions to develop policy in a particular program area. The ACRA or OCC may review all committee decisions.

10-10 EXPERT SUPPORT FOR CASES

10-10-1 Purpose

This section sets out a procedure for assuring that medical, scientific, technical or other specialized (collectively "expert") support is available for a case. A witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case (Federal Rules of Evidence, "Rule 702. Testimony by Experts").

For purposes of this section, the term "case" refers to a matter that is or may become a court case or hearing. The term "experts" is used to describe individuals from within or outside of FDA, who may serve as consultants and/or as expert witnesses in a case. FDA may seek expert support whether or not a case is contested or litigated.

10-10-2 Responsibility

The Centers have the primary responsibility for assuring that FDA has appropriate expert support for a case, if needed to support the particular violation. The initial determination as to the need for expert support shall be included in the approval memorandum. The Center Compliance Office, in consultation with OCC, should determine whether or not FDA needs expert support for a case. If the Center determines that expert support is needed, it should consult with its medical or scientific review staffs to ensure that the Center position on the subject represents the consensus of current informed medical or scientific opinion. If necessary, the Center should also consult the Office of Regulatory Affairs (ORA) district offices to make this determination (see also FDA Staff Manual Guide 2610.2, Obtaining Services of Expert or Fact Witnesses (7/2/98)).

The Center should also determine whether FDA will be able to obtain expert support for a case, when it is necessary to do so. The Center should not send a case forward to institute actual legal proceedings until it makes these determinations about expert support.

10-10-3 Criteria For Determining The Level Of Expert Support

FDA requires outside expert support in precedent-setting cases when FDA does not have sufficient in-house expertise. If in-house experts are available, the Center should contact them to determine whether it should also contact individuals from outside FDA to assess the consensus of current medical, scientific, or technical opinion.

The Center generally should review unprecedented issues and complex cases involving state-of-the-art and/or current good manufacturing practice to determine whether it should obtain concurrence by the experts.

The Center generally needs only limited additional expert support for cases that are sufficiently similar to previous cases, except where a new court decision, regulation, or policy has

sufficiently changed the factors to consider.

The Center generally needs to refer only to recent cases when determining the need for expert support in a current case that is identical to a recent case.

10-10-4 Documentation

The Center's approval memorandum for a case should include a section regarding expert support, under a separate heading. This section should summarize the Center's effort to provide assurance of expert support and describe significant issues or concerns related to the expert support. It should also include relevant information about prior or pending court cases, testimony or affidavits developed during a recent court case or hearing, information derived during recent processes to propose or finalize rules, advisory committee meetings, literature searches that support the consensus of current opinion, memoranda of conversations with experts, etc.

10-10-5 List Of Individuals For Expert Support

The Center should develop and maintain a list of experts. The Center might develop this information from a variety of sources, but it is responsible for assuring the adequacy of the expert support for a case. For example, when the Center contacts an expert, it should consider asking that expert to identify other individuals with similar expertise. This may be useful in the case at hand (e.g., if a corroborating witness is needed) as well as in future cases.

10-10-6 Obtaining And Paying For Expert Support

The Center might determine that FDA needs expert support from outside FDA to review a case and/or to serve as an expert witness. In that event, the Center should consult with other FDA components, e.g., Office of Chief Counsel and ORA district offices, to identify the most suitable witness, obtain the services of that individual, and pay for fees. Further background about obtaining the services of experts and paying for expert support is set out in an August 25, 2003, memorandum from Donald Vasbinder, Acting Director, Office of Enforcement, to FDA Center and ORA managers. A copy of the memorandum can be found on the Office of Enforcement's intranet web site.

As explained in that memorandum, it is important to keep in mind the overall principle that each case is brought on behalf of the FDA, not any particular part of the organization. It is the responsibility of all involved elements of the FDA to cooperate and work together to provide the best possible support for all cases, regardless of which particular office may be the lead. Thus, it is the joint responsibility of the Center and field offices to identify and obtain the best witnesses and other case support, with the Office of Chief Counsel responsible for the final determination of use of witnesses if we anticipate a contest or litigating a case. Although the Centers have primary responsibility for assuring the availability of expert support, field offices should work closely with the Centers and provide any possible assistance in the process, such as identifying and suggesting to the Center possible good local experts. Field/Center consultation and cooperation on considering the possible need for and the obtaining of expert support should start as soon as necessary and feasible in the case development process and continue throughout each stage.

The following procedures are to be followed for obtaining and paying for the services of experts when needed for support of court cases or hearings:

1. Decisions are to be made jointly by the responsible Center and field offices on the type and scope of expert support needed for support of cases and hearings. It is also important that, if the Agency anticipates that a case will be contested, the Office of Chief Counsel be consulted as to the use of expert witnesses. The office that first identifies the need to obtain expert support is responsible for contacting and consulting with the other offices responsible for the case.

2. For outside (non-FDA) consultants and expert witnesses agreed upon as necessary by all parties to support cases or hearings at any stage (including support for a recommendation, review and approval, and litigation), all costs associated with such services will be shared equally among each major office (other than OCC) having responsibility for the case (e.g., each Center and District involved). This includes all necessary expenses for such expert services, such as contracting for and consulting with experts, travel and per diem, and other associated expenses necessary for this purpose.

   a. For outside experts, the responsible Center and field offices involved shall also consult and agree with one another on which office will be designated to take the lead role in actually contacting the expert, negotiating a contract for services, and making sure the necessary paperwork is completed.

   b. Normally, unless mutually agreed otherwise, the designated lead office for these administrative purposes will be the one having primary responsibility for the aspect of the case that requires the expert support. For example:

      i. The District would normally be the administrative lead for expert support (such as declarations) required for its regulatory action recommendations, or for expert witnesses needed for testimony for a trial or hearing under the District's purview.

      ii. The Center would normally be the administrative lead if either the Center or OCC concluded in reviewing a recommended case that outside expert review is required to ensure adequate scientific support is available before proceeding with the case, or for expert witnesses needed for testimony at a hearing under the Center's purview.

   c. The designated lead office that prepares the necessary paperwork to procure the services for outside expert support is also responsible for ensuring timely payment of all invoices related to the services provided. In order to accommodate the shared-funding arrangement, the following accounting procedures should be employed:

      i. ***When an ORA field office is designated as the lead for an outside expert:***

      The total expense should be charged to the applicable ORA field central funding CAN using category E. Accounting technicians should code field "N" of the DHR as follows:

      "E (Last name of witness)"

      Copies of each obligating document, including information concerning the Center with which the cost will be shared, should be faxed to ORA's Office of Resource Management, Division of Management Operations (DMO) at (301) 827-1679. DMO will provide the respective Center a copy of the obligating document for tracking

purposes. Each quarter, DMO will contact the budget personnel in the applicable Center to request a transfer of funds to recover half of the total cost.

ii. ***When a Center is designated as the lead for an outside expert:***

The total expense should be charged to the applicable Center's accounting point. Copies of each obligating document, including information concerning the field location with which the cost will be shared, should be faxed to ORA's Office or Resource Management, Division of Management Operations (DMO) at (301) 827-1679. Each quarter, the applicable Center will contact the budget personnel in DMO (301-443-3350) to request a transfer of funds to recover its half of the total cost.

3. For expert support provided by FDA employees, all such expenses (including travel and per diem) will be borne by the office of the employee involved. Expenses should be paid by the employee's office in accordance with its normal procedures. (NOTE: For expert support by FDA employees, this changes some provisions in sections 5.b. and 7.b.iii. of Staff Manual Guide 2610.2, which are somewhat in conflict.)

10-11 TESTIMONY; PRODUCTION OF RECORDS; CERTIFICATION OF RECORDS

10-11-1 Requests for Testimony

FDA may authorize FDA employees to provide testimony if the testimony will be in the public interest and promote FDA's objectives (21 CFR 20.1). While interrupting the normal duties of FDA employees to provide testimony in a proceeding to which the agency is not a party is generally not considered to be in the public interest, FDA may be able to honor a request for testimony by providing responsive documents. FDA can also certify these documents for presentation in court.

FDA processes written requests for testimony in accordance with 21 CFR 20.1. Affidavits, declarations, and employees' responses to depositions, interrogatories, or rogatory letters are considered to be testimony covered by this regulation. (See Definitions) FDA does not process verbal requests for testimony.

FDA employees are not permitted to provide testimony pertaining to any function of the FDA, or with respect to any information acquired in performing their official duties, unless authorized by the Commissioner (21 CFR 20.1(a)), or another FDA official to whom this authority has been delegated.

The Director, Division of Compliance Policy (DCP), OE, ORA has been delegated the authority to authorize the giving of testimony under 21 CFR 20.1, and is the Agency lead for authorizing all testimony. In addition to the Director, DCP, the following officials have the authority to authorize the giving of testimony under 21 CFR 20.1: the Associate Commissioner for Regulatory Affairs (ACRA); the Deputy ACRA, ORA; and the Director and Deputy Director, Office of Enforcement (OE), ORA. See Staff Manual Guide 1410.24(a)(2)) for these delegations and SMG 1410.21 for General Redelegations of Authority from the Commissioner.

In addition to the DCP director's role in authorizing testimony, DCP conducts the initial review of all requests for testimony, except for requests from a state government agency.

The Division of Federal State Relations (DFSR) conducts the initial review of requests for testimony from a state government agency, and then prepares a 21 CFR 20.1 package for the review and signature of the Director, DCP, except as follows. If the testimony (e.g., affidavit, declaration) only addresses the absence of records or only identifies documents for the purpose of certifying records for a FOIA request, it does not require DCP (or OCC) review.

FDA employees may be asked to assist DCP and DFSR in responding to a request for testimony, by identifying suitable individual(s) to testify, drafting authorized testimony, or identifying records (instead of testimony) that are responsive to the request.

If a request involves Congress, employee personnel records, the DHHS Office of Equal Employment Opportunity, the investigation of an FDA employee by the DHHS Inspector General, the testimony of an FDA employee as a private citizen, or the testimony of a former employee regarding FDA-related matters, see the instructions in "Requests involving Special Circumstances" below. Otherwise,

1. ***If you receive a written request for testimony*** (whether by letter or subpoena) that was submitted by, or on the behalf of:

   a. A person *other than a state government agency*, contact DCP and send the request to that office.

   U.S. Food and Drug Administration
   Office of Enforcement
   Division of Compliance Policy (HFC-230)
   5600 Fishers Lane
   Rockville, MD 20857
   Phone: (240) 632-6860
   Facsimile: (240) 632-6861

   b. A state government agency, contact DFSR and send the request to that office.

   U.S. Food and Drug Administration
   Office of Regional Operations
   Division of Federal-State Relations (HFC-150)
   5600 Fishers Lane
   Rockville, MD 20857
   Phone: (301) 827-2898
   Facsimile: (301) 443-2143

2. ***If you are contacted by an individual requesting testimony:***

   a. Either refer the person to the Director, DCP or, as appropriate, the Director, DFSR; or advise them that FDA does not process verbal requests for testimony and that they should submit a written testimony request to the address for DCP or, if appropriate, DFSR shown above, well in advance of their desired due date to allow time for evaluating and processing the request; and that they should include information about the hearing body, date, location, and purpose of the proceeding; the nature and scope of the testimony FDA is being asked to provide and the use to which it will be put; the name(s) of the FDA employees, if known, being asked to testify; the requester's interest in the matter sought to be disclosed; the requester's rationale for considering that the testimony is in the public interest and will promote the objectives of FDA and the laws it enforces; and any other relevant background. Refer them to 21 CFR 20.1(c) for FDA's procedures on how to make these requests.

   b. Do ***not*** make any commitment regarding the availability or willingness of a witness to testify in any particular case.

   c. Document the conversation, and send DCP (or DFSR) a memorandum by email or facsimile at the telephone numbers above, and contact that office to confirm receipt.

3. ***If you have been authorized to testify:***

   a. Before presenting testimony, contact the assigned OCC attorney, if any, to obtain legal advice; and the appropriate FDA component, to obtain technical advice and, if needed, information about funding travel.

   b. After presenting testimony, submit a summary or copy of the testimony or a transcript of the testimony to DCP, OCC, and, if involved, DFSR. If the Director, DCP, authorizes the testimony for a hearing in a state court, the summary memorandum should address not only the individual's testimony, but also any other portions of the hearing that the individual attended.

10-11-2 Requests for Production of Records

The Director, DCP, is the Agency lead for responding to subpoenas for the production of records.

FDA processes requests for records in accordance with 21 CFR 20.2. This regulation provides that any request for FDA records, whether it be by letter or by a subpoena duces tecum or by any other writing, will be handled according to the FOIA provisions of 21 CFR Part 20.

If a request involves Congress, employee personnel records, the DHHS Office of Equal Employment Opportunity, the investigation of an FDA employee by the DHHS Inspector General, the testimony of an FDA employee as a private citizen, or the testimony of a former employee regarding FDA-related matters, see the instructions in "Requests involving Special Circumstances" below. Otherwise,

1. ***If you receive a written request or a subpoena, including a subpoena duces tecum, for the production or certification of records:***

   Send the request to the address for DCP or, if appropriate, DFSR shown above in "If you

receive a written request for testimony."

2. ***If you are contacted by an individual requesting the production or certification of records:***

   a. Either refer the person to the Director, DCP or, if appropriate, the Director, DFSR; or advise them that FDA does not process verbal requests for records and that they should submit a written request to the address for DCP or, if appropriate, DFSR (shown above in "If you receive a written request for testimony") well in advance of their desired due date to allow time for evaluating and processing the request; and that they should include specific information about the records requested, the requested due date, and any other relevant background. Refer them to 21 CFR 20.2 for FDA's procedures for processing these requests.

   b. Do ***not*** make any commitment regarding the availability of records.

   c. Document the conversation, and send DCP (or DFSR) a memorandum by email or facsimile (at the numbers shown above in "If you receive a written request for testimony"), and contact that office to confirm receipt.

10-11-3 Multi-issue Subpoena - Requests for Samples

If you receive a subpoena or a request that seeks FDA records, testimony, and actual samples, you should: (1) refer the sender of the request/subpoena for the samples to the Director, DCP, who, if needed, will consult with OCC for a response pursuant to 21 CFR 2.10, and if involved, OCI; and (2) process the remaining portion of the request/subpoena as a request for testimony and for records.

FDA considers a request/subpoena for analytical results to be a request for records.

10-11-4 Requests for Certification of Records

FDA processes requests for certification of records in accordance with 21 CFR 20.3. DCP will forward requests for the certification of records to the appropriate component for direct response.

10-11-5 Requests involving Special Circumstances

If you receive a request that involves:

1. An FDA proceeding or a DHHS proceeding where FDA is involved – contact OCC, if that office is not already involved or aware of the request.

2. Congress – contact FDA's Office of Legislation.

3. Employee personnel records related to litigation – contact the Employee and Labor Relations Branch in DHHS's Rockville Human Resources Center.

4. An investigation of an FDA employee by the DHHS Inspector General - contact FDA's Office of Internal Affairs (HFH-560) in the Office of Criminal Investigations.

5. The DHHS Office of Equal Employment Opportunity – contact FDA's EEO and Diversity Management Office (HF-15), in the Office of Shared Services.

6. Testimony as a private citizen - Some testimony as a "private citizen" (i.e., not in one's official FDA capacity) may raise special concerns such as possible conflict of interest or may require approval as an outside activity. NOTE: If the individual's planned testimony is based on information derived during FDA employment, the employee must contact the Office of Regulatory Affairs (ORA), Office of Enforcement (OE), Division of Compliance Policy (DCP) (HFC-230) for clearance of this testimony under 21 CFR 20.1. For testimony as a private citizen, employees also should refer to the Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR 2635.805, and the HHS Supplemental Standards of Ethical Conduct, 5 CFR 5501.106. Contact FDA's Ethics and Integrity Staff for further information regarding approval of the testimony as an outside activity.

7. Testimony by former FDA employees - Requests for the testimony of former FDA employees are not covered specifically by 21 CFR 20.1. Encourage former employees to contact the Office of Regulatory Affairs (ORA), Office of Enforcement (OE), Division of Compliance Policy (DCP) (HFC-230) if they receive a request or subpoena to provide testimony regarding FDA-related matters, because FDA may assist that individual. Advise former employees that there may be other restrictions on their ability to provide the requested testimony, including possible conflict of interest concerns and statutory and regulatory restrictions on the release of trade secrets and other kinds of confidential information.

10-11-6 Disclosure of Non-public information

FDA generally discloses information pursuant to a request or subpoena if that information is neither exempt from disclosure under FOIA nor prohibited from disclosure by other law. In certain circumstances, however, the law allows FDA to share certain non-public information that is otherwise exempt or prohibited from disclosure, e.g., 21 CFR 20.85 (disclosure to other federal agencies), 21 CFR 20.88 (disclosure to state and local agencies), or 21 CFR 20.89 (disclosure to foreign agencies). Other examples of instances in which FDA may share non-public information are set forth below.

1. FDA may share certain non-public information with federal or state officials commissioned by FDA under law.

2. FDA may share certain non-public information with other government officials under agreements or contracts that contain appropriate confidentiality provisions.

3. FDA may share personal privacy information that a state or federal prosecuting attorney seeks without redaction for use as evidence at trial, if the release is allowed under the Privacy Act (5 U.S.C. 552a). Contact OCC and FDA's Privacy Act Officer in DFOI before sharing this non-public information.

4. If OCI is involved in joint investigations with other law enforcement agencies for violations of the FD&C Act, contact OCI before sharing non-public information related to the investigation. Applicable regulations in 21 CFR Part 20, the law enforcement exemption of the Privacy Act, and 21 U.S.C. 331(j) govern disclosures of certain non-public information during the course of open multi-agency investigations. In all multiagency investigations, OCI has obtained or, prior to the sharing, will obtain confidentiality assurances that the non-public information disclosed by FDA will be used for law enforcement purposes only, and in accordance with the provisions of the applicable statutes.

10-11-7 Other Requests for Information – Informal Meetings

A person (individual, company, corporation, etc.) might request an informal meeting with an FDA employee to discuss information the employee obtained during the course of his or her employment.

1. If the requester is ***not*** an official from another government agency, and if private civil litigation is involved, decline the request and suggest that the requester submit a request for testimony under 21 CFR 20.1. Also, advise the requester that FDA has a long-standing policy against granting one-sided interviews or informal testimony to avoid creating the impression that FDA is biased toward a party.

2. If the requester is ***not*** an official from another government agency, if the request relates to a matter other than private civil litigation (e.g., the requester seeks general information about FDA's activities), advise the requester to submit a written request to FDA, to be handled as general correspondence under routine office procedures.

3. If the requester is an official from another government agency, advise the requester to submit a written request to FDA to be handled under appropriate agency procedures for the sharing of publicly releasable or non-public information. Contact OCI's information disclosure senior investigator if the request is from a law enforcement agency and the request is for non-public information.

4. Consult with DCP if needed.

10-11-8 Definitions

The following list contains definitions of commonly used terms in the context of testimony, subpoenas, or production of records.

Affidavit - A written document signed in the presence of a notary public under a sworn oath that the statement is true. FDA considers an affidavit to be testimony covered by 21 CFR 20.1.

Certification (also known as "certificate") - A written assurance, or official representation, that some act has or has not been done, or some event occurred, or some legal formality has been complied with. Typically, a requester will ask that FDA certify as to the authenticity of an FDA record as a true copy. FDA processes requests or subpoenas for certification under 21 CFR 20.3.

Declaration - A written statement signed under the penalty of perjury. A declaration can substitute for an affidavit in federal court proceedings. 28 U.S.C. 1746. FDA considers a declaration to be testimony covered by 21 CFR 20.1.

Deposition - The taking and recording of testimony of a witness under oath, in front of a court reporter prior to trial and away from the courtroom. FDA considers an employee's responses in a deposition to be testimony covered by 21 CFR 20.1.

Interrogatories - Written questions sent by one party in a lawsuit to the other party during the discovery process prior to trial. Interrogatories must be answered in writing under oath or under penalty of perjury. FDA considers the employee's response to interrogatories to be testimony covered by 21 CFR 20.1.

Notary Public - A person authorized by the state in which they reside to administer an oath of truth to a person making an affidavit, and to apply their signature and seal or stamp to attest to the oath.

Rogatory Letters - A written request from a judge in one state to a judge in another, asking that the latter take the testimony of a witness. FDA considers testimony in response to rogatory letters to be covered by 21 CFR 20.1.

Subpoena - A court order commanding a witness to appear at a certain time and place to testify on a certain matter. For purposes of this section, a "subpoena" means a subpoena for verbal or written testimony (e.g., an affidavit). A subpoena for testimony also might include a request for records. In that case, FDA would process the subpoena under 21 CFR 20.1 and 20.2.

Subpoena Duces Tecum - A court order commanding a witness to produce documents at a certain time and place. FDA processes these subpoenas, which are intended for the production of records, under 21 CFR 20.2.

Testimony - For purposes of this section, testimony is an individual's statement given in writing (such as an affidavit or a declaration) or by appearance under oath at a proceeding. The statement might be in response to a deposition or interrogatories. Testimony is covered by 21 CFR 20.1.

10-11-9 References

1. "Enforcement Notes," Issue No. 85, September 18, 2002, Testimony, available on ORA's Intranet
2. Staff Manual Guide 1410.21(General Redelegations of Authority from the Commissioner to other Officers of the Food and Drug Administration)
3. Staff Manual Guide 1410.23 (Certification of True Copies and Use of Department Seal)
4. Staff Manual Guide 1410.24 (Disclosure of Official Records and Authorization of Testimony)
5. Staff Manual Guide 2127.1 (Attendance by FDA Employees at Congressional Hearings)
6. Staff Manual Guide 2127.2 (Requests for Testimony of FDA Personnel in Non-FDA Proceedings)
7. Staff Manual Guide 2460.7 (Procedures for Implementing the Freedom of Information Act) (Not on Intranet)
8. 5 U.S.C. 552a (Privacy Act); 21 CFR Part 21(Privacy Act regulations)
9. 5 U.S.C. 552(b) (Freedom of Information Act (FOIA)); 21 CFR Part 20 (FOIA regulations), particularly 21 CFR 20.1, 20.2, and 20.3
10. 5 CFR 2635.805 (Standards of Ethical Conduct for Employees of the Executive Branch; Service as an expert witness)
11. 5 CFR 5501.106 (HHS Supplemental Standards of Ethical Conduct; Outside employment and other outside activities

12. Information Disclosure Manual on ORA's Intranet Information Disclosure Main Page
13. FDA's FOIA Page on FDA's Intranet

10-12 APPLICATION INTEGRITY POLICY

The Application Integrity Policy (AIP) describes the Agency's approach regarding the review of applications that may be affected by wrongful acts that raise significant questions regarding data reliability. FDA published this policy, formally entitled, "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy" in the Federal Register on September 10, 1991 (56 FR 46191), and in Compliance Policy Guide (CPG) 7150.09 (see Sec. 120.100 of the Compliance Policy Guides publication). These documents, procedures to implement the AIP, and AIP information are available on the Internet at: http://www.fda.gov/ora/compliance_ref/aip_page.html.